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Original article

Linguistic and content validation of the translated and culturally adapted PG-SGA, as perceived by Norwegian cancer patients and healthcare professionals

Christine Henriksen ^{a,*}, Lene Thoresen ^b, Berit Fjoseide ^a, Sissi Stove Lorentzen ^c, Trude Rakel Balstad ^{b,d}, Faith D. Ottery ^e, Harriët Jager-Wittenaar ^{f,g}^a University of Oslo, Department of Nutrition, Oslo, Norway^b Cancer Clinic, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway^c Lovisenberg Diaconal Hospital, Oslo, Norway^d Department of Clinical and Molecular Medicine, Faculty of Medicine and Health Sciences, NTNU – Norwegian University of Science and Technology, Trondheim, Norway^e Ottery & Associates, LLC, Deerfield, IL, USA^f Hanze University of Applied Sciences, Research Group Healthy Ageing, Allied Health Care and Nursing, Groningen, the Netherlands^g University of Groningen, University Medical Center Groningen, Department of Oral and Maxillofacial Surgery, Groningen, the Netherlands

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SUMMARY

Background & aims: The Scored Patient-Generated Subjective Global Assessment (PG-SGA®) is a validated nutritional screening, assessment, monitoring, and triage tool. When translated to other languages, the questions and answering items need to be conceptually, semantically, and operationally equivalent to the original tool. In this study, we aimed to assess linguistic and content validity of the PG-SGA translated and culturally adapted for the Norwegian setting, as perceived by Norwegian cancer patients and healthcare professionals (HCPs).

Methods: We have translated and culturally adapted the original PG-SGA for the Norwegian setting, in concordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Cancer patients and HCPs, including nurses, dietitians and physicians, were invited to participate. Comprehensibility and difficulty were assessed by patients for the patient component (PG-SGA Short Form), and by HCPs for the professional component. Content validity was assessed for the full PG-SGA by HCPs only. The data were collected by a questionnaire and evaluations were operationalized by a 4-point scale. Item and scale indices were calculated for comprehensibility (Item CI, Scale CI), difficulty (Item DI, Scale DI) and content validity (Item CVI, Scale CVI).

Results: Fifty-one cancer patients and 92 HCPs participated in the study. The patients perceived comprehensibility and difficulty of the Norwegian PG-SGA Short Form as excellent (Scale CI = 0.99 and DI = 0.97). However, HCPs perceived comprehensibility and difficulty of the professional component as below acceptable (Scale CI = 0.78 and DI = 0.66), and the physical exam was being rated as the most difficult part (Item DI 0.26 to 0.65). Content validity for the full Norwegian PG-SGA was considered excellent (Scale CVI = 0.99) by the HCPs.

Conclusion: The patient component of PG-SGA was considered clear and easy to complete, and the full Norwegian PG-SGA was considered as relevant by HCPs. In the final Norwegian PG-SGA, changes have been made to improve comprehensibility of the professional component. To improve perceived difficulty of completing the professional component, training of professionals is indicated.

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Abbreviations: PG-SGA, Patient-Generated Subjective Global Assessment; SF Short Form, ISPOR International Society for Pharmacoeconomics and Outcomes Research; HCP, healthcare professionals; CI, Comprehensibility Index; DI, Difficulty Index; CVI, Content Validity Index.

* Corresponding author. University of Oslo, Department of Nutrition, Box 1046 Blindern, N-0317, Oslo, Norway.

E-mail address: christine.henriksen@medisin.uio.no (C. Henriksen).

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Introduction

Malnutrition is a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat-free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease [1]. Disease-related malnutrition is frequent in cancer patients, with estimated rates ranging from 20 to 70%, depending on diagnosis, stage and age, as well as the method of assessment [2]. Guidelines by the European Society for Clinical Nutrition and Metabolism (ESPEN) on nutrition in cancer strongly recommend routine screening of cancer patients due to a possible beneficial effect of individual nutritional support [2]. Such screening aims for early detection of malnutrition and initiation of nutritional treatment. Nutritional risk screening followed by individual nutritional support is associated with improved nutritional status, quality of life, and reduced length of hospital stay, lower morbidity and mortality [3–5].

Within the oncology setting, the Scored PG-SGA has been acknowledged worldwide as the reference method to assess malnutrition [6–9]. The Scored PG-SGA is a two-paged tool, which can be used for screening, assessment, and monitoring of malnutrition. Based on the total PG-SGA score, the tool also gives recommendations for the indicated nutrition interventions [10]. While the PG-SGA was first validated in patients with cancer, subsequently the PG-SGA has also been validated for other populations, and the use is now comprising acute care setting, chronic obstructive pulmonary disease, dysphagia, nephrology, neurology, and elderly patients, amongst others [11–15].

The increasing use of the PG-SGA internationally necessitates validated translations to other languages. This work is now in progress in many countries worldwide. The PG-SGA has already been officially translated and culturally adapted to the Dutch, Portuguese, Thai, and German setting [16–18], and others are currently in process. These language versions of the PG-SGA have been developed according to the principles of good practice for the translation and cultural adaptation process for patient-reported outcome measures by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), to ensure good methodological quality [19]. Before applying a translated and culturally adapted instrument in clinical practice and research, linguistic and content validity must be confirmed. While content validity testing aims to assess relevance of the translated and culturally adapted instrument perceived by the target group, linguistic validation aims to determine conceptual and semantic equivalence of the translated and culturally adapted instrument to the original version. Hence, the purpose of the complete process of translation, cultural adaptation and linguistic and content validation is to produce a conceptual, semantic, and operational equivalence to the original tool [10,20].

Thus far, no official and validated Norwegian version of the PG-SGA existed. Therefore, we have translated and culturally adapted the original PG-SGA for the Norwegian setting. In this study, we aimed to assess linguistic and content validity of the PG-SGA translated and culturally adapted for the Norwegian setting, as perceived by Norwegian cancer patients and healthcare professionals (HCPs).

Methods

Translation and cultural adaptation

The translation and cultural adaptation process of the PG-SGA for the Norwegian setting has been conducted according to the International Society for Pharmacoeconomics and Outcomes

Research (ISPOR) guideline “Translation and Cultural Adaptation of Patient-Reported Outcomes Measures – Principles of Good Practice”, hereby referred to as the ISPOR principles [19], following the same methodology as the development of the Dutch version of the PG-SGA [16]. The ISPOR Principles describe a consensus of a translation and cultural adaptation process based on strengths and weaknesses of existing methodologies. The ten steps in the translation and cultural adaptation process according to the ISPOR principles are: 1) preparation, 2) forward translation, 3) reconciliation, 4) back translation, 5) back translation review, 6) harmonization, 7) cognitive debriefing, 8) review of cognitive debriefing, 9) proofreading, and 10) final report [19].

Steps 1 to 6 of this framework have been conducted prior to the commencement of the present study, and resulted in a preliminary Norwegian version of the original English metric PG-SGA (version 3.22.15).

The linguistic and content validation reported here include step 7 to 9 of the ISPOR principles. These steps were conducted using the draft metric Norwegian version of the PG-SGA (version 01.18.17). Step 7 comprises cognitive debriefing of the new translation with participants from the target population, which in this context were cancer patients and HCPs. Step 7 also includes assessment of content validity as perceived by the HCP. The purpose of this step is to ensure that the translation is comprehensible and easy to complete according to both the patients and HCP, and that the HCP perceive the Norwegian PG-SGA as relevant.

In step 8 – Review of cognitive debriefing results and finalization – the findings of the debriefing process were incorporated to improve the wording in the Norwegian PG-SGA. The findings were reviewed against the original version of the instrument to assure the cultural content validity. Based on the respondents' comments, necessary modifications for improvement of the translated items were discussed with, proofread (step 9) and approved by the creator the PG-SGA.

The study sample

A convenient sample of patients with different cancer diagnoses and stages of disease, including cancer survivors, were invited to ensure a heterogeneous cancer population. The participants were recruited between January and June 2017, from Vardesenteret, an outpatient support center for cancer patients and their caregivers, and at the Cancer Clinic, St. Olavs University Hospital, Trondheim, Norway.

The inclusion criteria were: patients or former patients with any diagnosis of cancer that were Norwegian speaking and above 18 years of age.

To assess cognitive function, the Mini Mental Status Evaluation (MMSE) was performed. The official revised Norwegian version of MMSE (MMSE-NR3) was used [21]. This version consists of 20 questions the subject is to answer, and maximum score is 30 points. A score below 24 indicates a cognitive failure, a reading- or writing disability or other conditions that may affect the test results. The cut-off was set to 24 to exclude the participants with conditions that could interfere with understanding the PG-SGA form for other reasons than the language and layout itself. The cognitive evaluation was performed one-to-one in a private room.

Recruiting of HCPs took place between January and August 2017. The composition of the sample of HCPs was attempted to be multidisciplinary, and consisted of clinical dietitians, physicians, nurses, and students in these fields. They were preferably nurses and physicians working with cancer patients and clinical dietitians working in a clinical setting.

Linguistic and content validation of the PG-SGA

The Scored PG-SGA form is two-paged, whereof page one alone is referred to as the PG-SGA Short Form (SF) and is exclusively patient-generated. In the four boxes of the PG-SGA SF, the patients give information about their current and former weight (Box 1), change in food intake and current type of food/nutritional intake (Box 2), symptoms that impact food intake (Box 3), and level of activity and function (Box 4). The PG-SGA SF consists of totally 9 items to be filled out by the patient, hereby called the “patient component”.

On page two, which include five “worksheets”, is completed by the HCPs, by scoring weight loss, assessment and evaluation of the patient's diagnosis, metabolic demands, and performing a nutrition-focused physical examination. Finally, the total PG-SGA score is summarised, and the patient is categorised as Stage A: Well nourished, Stage B: Moderate or suspected malnutrition, or Stage C: Severely malnourished [3]. These five worksheets and the nutritional triage recommendations are hereby called the “professional component”. The patient and professional component together are known as the Full PG-SGA.

Questionnaires to collect demographic information from patients and HCP as well as responses to questions on comprehensibility, difficulty and content validity of the PG-SGA were based on the methodology used by Sealy et al. in the pilot testing of the Dutch PG-SGA [16]. For the current study, texts in these questionnaires were taken from the Norwegian translated PG-SGA (15-004 v01.18.17).

Three constructs were used to evaluate the items in the Norwegian PG-SGA, in accordance with the methodology used in earlier studies [16].

1. Comprehensibility – how clearly is the item described in the instrument?
2. Difficulty – how difficult is it to answer the item, does the respondent need more knowledge or skills to be able to answer the item?
3. Content validity – does the respondent consider the item relevant to the concept of malnutrition?

Comprehensibility and difficulty of the 36 items in the patient component were assessed by cancer patients, and content validity of the patient component was assessed by HCP. Furthermore, HCPs evaluated all aspects of the 38 items in the professional part of the PG-SGA. The questionnaire also contained open-ended fields for comments after each box/worksheet.

The testing of comprehensibility, difficulty, and content validity of the Norwegian PG-SGA were operationalized by a 4-point Likert scale, as shown in Table 1.

Statistics

Before calculating item and scale scores, scores of 1 and 2 were recoded to 0, indicating ‘not present’. Similarly, scores of 3 and 4 were recoded to 1, indicating ‘present’, as described earlier by Sealy et al. [16]. Item indices were calculated by dividing the number of respondents who considered the item to be “present” by the total number of respondents. Indices were calculated for each item for comprehensibility (I-item CI), difficulty (Item DI), and content validity (Item CVI).

The scale index of each construct was calculated by averaging all the item indices for the respective construct (Scale CI, Scale DI, and Scale CVI). Since the patient group evaluated the patient component of the PG-SGA, the patient scale indices are only referring to the PG-SGA SF. For the HCPs, separate scale indices were calculated

for PG-SGA SF and the professional component respectively, in addition to a total scale index for the full PG-SGA. Item indices <0.78 required further analysis of the item. Scale indices 0.80–0.89 were considered acceptable and ≥ 0.90 as excellent [16]. Calculation of the index scores was performed in Excel.

Continuous variables are presented as means and range. Categorical variables are presented as frequencies (number) and percentage. The independent sample t-test was used to analyse differences between subgroups. Statistical analyses were performed by using SPSS version 25. The level of statistical significance was set at a p-value of <0.05 for all analyses.

Ethics

The Regional Committee for Medical and Health Research Ethics evaluated the protocol and concluded that no national ethical approval was required for this study (Reference 2016/2017 REK), since the study was not within the scope of the Norwegian Health Research Act. The study was ethically approved by the local review board at the Cancer Clinic, St. Olavs Hospital, Trondheim University Hospital. The patients and HCPs received written information, consented to participate, and answered all questionnaires anonymously.

Results

In the patient group, a total of 51 participants completed the questionnaire. Characteristics of patients are described in Table 2. Four patients did not conduct the cognitive function evaluation, for practical reasons. The remaining 47 patients all had a MMSE score ≥ 24 . The majority of the participants was female (75%) with a relatively high level of education.

The 92 healthcare professionals that participated in the study included nurses, clinical dietitians, physicians, and students in these professions. Characteristics of the HCPs are described in Table 3. The mean number of years of experience within their respective fields was 13.2 (SD: 10.8) years. A total of 40% of the HCPs were familiar with the PG-SGA from literature, courses, or other sources (e.g., own research). However, 71% of the HCPs who were familiar with the PG-SGA reported that they had not used it themselves in clinical practice (Table 3).

The comprehensibility, difficulty, and content validity indices for the PG-SGA SF as reported by the patients and HCPs are presented in Table 4. Comprehensibility and difficulty of the patient component were perceived by the patient group as excellent, with Scale CI = 0.99 and Scale DI = 0.98. No item indices were below acceptable range (<0.80). Content validity for the patient component as perceived by the HCPs was excellent, with scale CVI = 0.99.

The results for the professional component of the PG-SGA are presented in Table 5. Overall, the HCPs perceived comprehensibility and difficulty of the worksheets as not acceptable (Scale CI = 0.78, Scale DI = 0.66). In total, 20/38 items had low comprehensibility and 23/38 items were considered as difficult, where of the physical exam in Worksheet 4 was considered the most difficult part (Item DI = 0.26 to 0.65). The primary disease staging in Worksheet 2 was

Table 1

Likert scale points for the constructs comprehensibility, difficulty, and content validity.

Likert scale points	Comprehensibility	Difficulty	Content validity
1	Very unclear	Very difficult	Very irrelevant
2	Unclear	Difficult	Irrelevant
3	Clear	Easy	Relevant
4	Very clear	Very easy	Very relevant

Table 2

Characteristics of the patient group (n = 51).

Variables	Mean/median	Standard deviation/IQR
Age, years	55.7	16.8
BMI, kg/m ^{2a}	24.6	4.1
Time since diagnosis, months (median)	12	6–39
	Number	%
Gender		
Female	38	75
Education ^b		
University level	30	61
Upper secondary school	15	31
Primary school or other	4	8

BMI = Body mass index, IQR = Interquartile range.

^a n = 50.^b n = 49.**Table 3**

Characteristics of the healthcare professionals (n = 92).

Variables	N	%
Profession		
Nurse	42	46
Clinical dietitian	26	28
Physician	21	23
Student, clinical nutrition	2	2
Student, other	1	1
Familiarity with PG-SGA ^a		
Yes, from literature	12	14
Yes, has been on course	1	1
Yes, other	22	25
No	53	60
Experienced in use of PG-SGA ^b		
Yes, use in patients myself	5	6
Yes, observed someone else using	1	1.1
Yes, other	5	5.5
No	80	87.9

^a n = 88.^b n = 91.

also regarded as quite difficult (Item DI = 0.58). However, difficulty of the Global Assessment Categories was considered as acceptable (Item DI = 0.81).

Content validity was considered excellent by HCPs for both the patient component (Scale CVI = 0.99) and the professional component (Scale CVI = 0.92), resulting in a scale CVI = 0.96 for the full PG-SGA.

No significant differences in scale indices ($p > 0.05$ for all) were found between the dietitians, physicians, and nurses regarding the professional component of the PG-SGA, nor for prior familiarity with the PG-SGA (Table 6).

The comments from the healthcare professionals and patients (data not shown) reflected some of the reasons for the low scoring of indices. These comments were helpful in elaborating and clarifying how the items could be better adapted and adjusted to the Norwegian setting. For instance, in question 2 about Food intake, the Norwegian wording of answering item “higher than usual” was changed to “more than usual”, and “normal intake” was changed to “usual intake”. Moreover, in the professional component, the Norwegian wordings in the instructions for scoring were also revised after the linguistic validation. The feedback from the patients and HCPs were used to finalize the culturally adapted and linguistically validated version of the Norwegian Scored PG-SGA. The findings were reviewed against the original version, which was approved as the final version of the Scored PG-SGA (18-004 v05.01.18) to be used in the Norwegian setting.

Discussion

In this linguistic and content validation of the Norwegian version of the PG-SGA, the patient component of the PG-SGA, was considered comprehensible and easy to complete by the patient. However, regardless of any or type of previous experience with the PG-SGA and despite considering the full PG-SGA as very relevant, HCPs perceived the professional component of the Norwegian version of the PG-SGA as unclear and difficult. In total, 60% of the items was considered as unclear half of the items were difficult to understand, and, in which no differences between the types of HCPs were found.

The high scores on comprehensibility and difficulty indices of the patient component of the PG-SGA was in line with results from two previous studies [16,17]. While the Scale CI was 0.98 in the present study, it was 0.99 and 0.96 in the Dutch and German study respectively [16,17]. Likewise, the scale DI was 0.99 in the present study, compared to 0.96 and 0.91 in the other studies [16,17]. This indicates that the patient component is feasible to complete by patients from different countries and cultures. The fact that HCPs considered the patient component as highly relevant, is also in line with studies from the other countries [16,17].

In contrast, the HCPs perceived comprehensibility and difficulty of the professional component as not acceptable. The scale CI was 0.78, and even lower than the Dutch and German study (0.81 and 0.87 respectively) [13,14]. In the current study, the scale DI was 0.66, which is just in between the Dutch and German results (i.e., 0.55 and 0.72) [16,17].

We did not find any significant difference between type of HCPs or familiarity with the PG-SGA. In our study, the familiarity with PG-SGA came mainly from the literature, and only 5 participants had actually tried the method before. The results of the current study supports the recommendation to train HCPs in the use of the PG-SGA prior to using it in daily practice [16]. A study in Dutch dietitians has demonstrated that already a full day training is very effective in improving both comprehensibility and difficulty of the PG-SGA [22].

Not surprisingly, the physical exam in Worksheet 4 was the component that scored the lowest in the constructs of comprehensibility and difficulty. All items on the construct of difficulty and 15 out of 17 items for the construct of comprehensibility had score indices <0.80. The comprehensibility score was consistently higher than the difficulty score, meaning the physical examination was in some cases clear, but difficult to perform. This is also in concordance with the Dutch and German study [16,17]. But while in the Dutch study [16] the HCPs evaluated content validity of the items in Worksheet 4 as below acceptable, the Norwegian HCPs evaluated these items as relevant in determining the nutritional status in cancer patients.

After the PG-SGA was developed, objective methods for assessing muscle mass beyond historically used anthropometric measurements, such as bioelectrical impedance analysis (BIA), computerised tomography (CT) and dual energy x-ray absorptiometry (DXA) have been more common to use in clinical practice or research settings. This development may have led the HCP to have less confidence in their own skills to perform a physical examination of muscle mass. It is also possible that some HCPs simply never taught how to perform this type of examination. The availability of objective methods may also partly explain why the Worksheet 4 receives the lowest content validity score.

Implications of the translated and culturally adapted tool

The original English version of PG-SGA has been widely validated with regard to concurrent validity, comparing the PG-SGA

Table 4
Indices for comprehensibility, difficulty, and content validity for the patient component of the Norwegian Patient-Generated Subjective Global Assessment.

Items	Patients (n = 51)		Healthcare professionals (n = 92)
	CI	DI	CVI
Box 1: Weight			
I currently weigh about _kg	1.00	0.96	1.00
I am about _cm tall	1.00	1.00	1.00
One month ago, I weighted about _kg	1.00	0.98	1.00
Six month ago, I weighted about _kg	1.00	0.90	1.00
Weight (decreased/not changed/increased)	0.98	0.96	0.98
Box 2: Food intake			
As compared to my normal intake,	0.96	0.91	0.99
I would rate my food intake during the past month as			
Unchanged/more than usual/less than usual	1.00	0.94	1.00
I am now taking	0.94	0.87	0.95
2a Normal food, but less than normal amount	0.96	0.94	0.98
2b Little solid food	0.98	1.00	0.98
2c Only liquids	1.00	1.00	0.99
2d Only nutritional supplements	1.00	1.00	1.00
2e Very little of anything	1.00	1.00	1.00
2f Only tube feeding or nutrition by vein	1.00	1.00	1.00
Box 3: Symptoms			
I have the following problems that have kept me from eating enough during the past 2 weeks	0.96	0.98	1.00
3a No problems eating	1.00	1.00	1.00
3b No appetite. Just did not feel like eating	0.98	0.96	1.00
3c Nausea	0.98	0.98	1.00
3d Vomiting	1.00	1.00	1.00
3e Constipation	0.98	0.98	1.00
3f Diarrhoea	1.00	1.00	0.99
3g Mouth sores	0.98	0.98	1.00
3h Dry mouth	1.00	1.00	1.00
3i Things taste funny or have no taste	1.00	0.98	0.98
3j Smells border me	1.00	1.00	0.98
3k Feel full quickly	1.00	1.00	0.99
3l Problems swallowing	0.98	1.00	1.00
3m Fatigue	1.00	0.98	0.98
3n Pain, where?	1.00	1.00	0.98
3° Other	0.96	1.00	0.99
Box 4: Activities and Function			
Over the past month. I would generally rate my activity as	1.00	0.98	1.00
4a Normal with no limitations	0.96	0.94	1.00
4b Not my normal self, but able to be up and about with fairly normal activities	0.94	0.96	0.99
4c Not feeling up to most things, but in bed of chair less than half the day	0.98	0.98	0.98
4d Able to do little activity and spend most of the day in bed or chair	1.00	0.98	1.00
4e Pretty much bedridden, rarely up of bed	1.00	1.00	1.00
Scale Indices patient component	0.99	0.98	0.99

CI: Comprehensibility Indices, DI: Difficulty Indices, CVI: Content Validity Indices.

with reference methods, and its ability to predict clinical outcomes [10]. When translated to other languages, linguistic validity is necessary to maintain the original meaning, purpose, and intention of the tool [19]. In addition, training of HPCs prior to clinical use also seems important, particularly for the aspect of the physical examination.

Other types of psychometric validations i.e., reliability-tests, are also important but were not conducted in the present study. An earlier study has tested criterion-validity on the question of food intake, and found a good association with energy- and protein intake measured with 24 h recall [23]. The physical examination part showed good agreement with low muscle mass assessed by CT, in an out-patient clinic for colorectal cancer patients in Brazil [24]. In contrast, low agreement between PG-SGA and muscle mass assessed by BIA, was found among colorectal patients in Norway, especially among overweight persons [25]. Validation of the PG-SGA is an ongoing process, and further studies of the psychometric properties of the tool are required.

The availability of culturally adapted and linguistically validated versions of PG-SGA in new languages will increase the use of the

PG-SGA in clinical and research settings. Data will be comparable across nations in cross-cultural research, in multicentre studies, or meta-analyses. A great advantage with this tool is the patient involvement in filling out the Short Form, which makes it suitable at all health care levels including home nursing setting [26,27].

Strengths and limitations with the study

The systematic approach of following the ISPOR principles has given this study strength and makes it comparable to the other translations and cultural adaptations of the PG-SGA to other country settings. Even though the PG-SGA includes a professional component, the ISPOR steps that were originally developed for patient-reported outcome measures, i.e., PROMs, have been able to provide an accurate linguistic validation also of this component of the PG-SGA. The steps for forward translation, reconciliation and back translation are uniform and should be transmissible to other types of instruments, not limited to PROMs only [28].

Another strength of this study is the large sample size of the HCP group. In addition to the fact that they were recruited from different

Table 5

Indices for comprehensibility, difficulty and content validity for the professional component of the Norwegian Patient-Generated Subjective Global Assessment.

Items	Healthcare professionals (n = 92)		
	CI	DI	CVI
Worksheet 1 – Scoring Weight Loss	0.78	0.71	0.98
Worksheet 2 – Disease and its relation to nutritional requirements	0.91	0.92	0.99
2a Cancer	0.97	0.97	0.98
2b AIDS	0.96	0.97	0.98
2c Pulmonary or cardiac cachexia	0.70	0.68	0.99
2d Chronic renal insufficiency	0.99	0.93	0.98
2e Presence of decubitus, open wound or fistula	0.94	0.92	0.99
2f Presence of trauma	0.89	0.85	0.98
2g Age greater than 65	0.99	0.98	0.93
2h All relevant diagnoses	0.75	0.73	0.94
2i Primary disease staging	0.57	0.58	0.88
Worksheet 3 – Metabolic Demand	0.69	0.67	0.95
3a Fever	0.96	0.93	0.98
3b Fever duration	0.93	0.88	0.98
3c Corticosteroids	0.88	0.84	0.96
Worksheet 4 – Physical Exam	0.61	0.26	0.93
4a Temples (temporalis muscles)	0.61	0.40	0.82
4b Clavicles (pectoralis & deltoids)	0.72	0.42	0.84
4c Shoulders (deltoids)	0.72	0.45	0.84
4d Interosseous muscles	0.51	0.33	0.80
4e Scapula (latissimus dorsi, trapezius, deltoids)	0.68	0.39	0.85
4f Thigh (quadriceps)	0.75	0.51	0.87
4g Calf (gastrocnemius)	0.73	0.51	0.89
4h Global muscle status rating	0.64	0.41	0.86
4i Orbital fat pads	0.51	0.32	0.80
4j Triceps skinfold	0.65	0.46	0.85
4k Fat overlying lower ribs	0.65	0.44	0.85
4l Global fat deficit rate	0.61	0.33	0.86
4m Ankle edema	0.83	0.65	0.93
4n Sacral edema	0.69	0.51	0.87
4° Ascites	0.81	0.56	0.92
4p Global fluid status rating	0.72	0.55	0.90
Worksheet 5 – PG-SGA Global Assessment Categories			
Stage A: well nourished. Stage B: moderate/suspected malnourished. Stage C: Severely malnourished	0.87	0.81	0.98
Nutritional Triage Recommendations	0.81	0.74	0.98
Triage 0–1: No intervention required at this time. Re-assessment in routine and regular basis during treatment	0.95	0.95	0.99
Triage 2–3: Patient, family education by dietitian, nurse or other clinician with pharmacologic intervention as indicated by symptom survey (box 3) and lab values as appropriate	0.80	0.81	0.98
Triage 4–8: Requires intervention by dietitian, in conjugation with nurse or physician as indicated by symptoms (box 3)	0.89	0.89	0.96
Triage >9: Indicates a critical need for improved symptom management and/or nutrient intervention options	0.92	0.91	0.96
Scale Indices professional component	0.78	0.66	0.92

* Indices below acceptable range are marked in bold. CI: Comprehensibility Indices, DI: Difficulty Indices, CVI: Content Validity Indices.

hospitals all over Norway, meaning that the data can be considered highly representative for the healthcare professional population in Norway.

A third strength is that we included multiple types of cancer patients and stages, to make the sample as representative as possible. The use of cognitive testing prior to completing the questionnaires ensured reliable results. Although cognitive status was missing for 4 patients, their results did not significantly differ from the total group. Furthermore, we included a much larger

sample than the six steps suggested by the ISPOR Principles, to gain insights from a larger sample size.

A potential limitation is the selection bias. In the patient group, recruiting most of the patients from one place gives the possibility of a convenience sample. Also, the patient group, being a highly educated one, in theory may have contributed to perceive the PG-SGA SF as easier as and more comprehensible than the average cancer patient. However, a study in Dutch patients with head and neck cancer, in which only 27% had a higher education level, perceived the patient component of the PG-SGA as very easy to complete [29]. Due to the recruitment strategy, the median time since diagnosis was about one year, indicating a relatively healthy study population. However, results from a qualitative study indicates that the PG-SGA SF is easy to use and understandable even for cancer patients that are severely ill [30].

The uneven distribution of professions in the HCP group represents the real-life distribution in hospitals (42 nurses versus 21 physicians). This resulted in low statistical power for this sub analyses, and small differences between groups cannot be ruled out. If differences between professions were large, they would however have been detected.

Table 6

Comprehensibility, difficulty, and content validity per profession and prior familiarity with the PG-SGA.

	Scale CI	Scale DI	Scale CVI
Profession			
Clinical dietitians (n = 26)	0.78	0.64	0.92
Physicians (n = 21)	0.77	0.65	0.92
Nurses (n = 42)	0.77	0.65	0.92
Experience			
Unfamiliar (n = 53)	0.78	0.66	0.92
Familiar (n = 35)	0.78	0.66	0.92

CI: Comprehensibility Indices, DI: Difficulty Indices, CVI: Content Validity Indices.

Conclusion

The patient component of the Norwegian PG-SGA is considered as clear and easy to complete by patients and relevant by HCPs, but HCPs evaluated the professional component of the PG-SGA to be incomprehensible and difficult to complete, regardless of any or type of previous experience with the PG-SGA and type of HCP. In the final Norwegian PG-SGA (18-004 v03.13.18), changes have been made to further improve comprehensibility of the worksheets for HCPs. To further improve perceived difficulty, training of professionals in completing the worksheets is indicated.

Statements of authorship

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Declaration of Competing Interest

F.D. Ottery is copyright holder of the PG-SGA and co-owner and co-developer of the PG-SGA-based Pt-Global app/web tool. H. Jager-Wittenaar was co-developer of the PG-SGA-based Pt-Global app/web tool. The other authors report no conflicts of interests to declare.

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